Remarks/Arguments

The foregoing amendments to the claims are of formal nature, and do not add new matter. Claims 119-138 are pending in this application and are rejected/objected to on various grounds. Claims 124 -131 are allowed. Claims 127-128, 132-134 have been canceled without prejudice or disclaimer, to claim its subject matter in subsequent continuation or divisional applications. Claims 139-145 have been added, support for which is found in canceled claim 132 and in the instant specification at page 285, line 11 onwards. Entry of these claims is respectfully requested. Accordingly, Claims 119-126, 129-131, 135-145 are now pending in this application. Claims 119-128 have been amended for clarity to particularly claim what the Applicants consider is their invention and further, with the recitation "wherein said nucleic acid is amplified in lung tumors." Support for this is found in Example 170 of the instant specification. The rejections to the presently pending claims are respectfully traversed.

Priority

Applicants submit that they rely on the gene amplification assay for patentable utility which was first disclosed in U.S. Provisional Application 60/141,037, filed June 23, 1999, priority to which has been claimed in this application. Based on the disclosure of SEQ ID NO: 24 and 25 or Figures 15 and 16 (that encodes PRO830) in Application 60/141,037 and the gene amplification assay, Applicants believe that the application provides adequate support for the nucleic acids encoding PRO830. Hence, Applicants should be entitled to at least an effective filing date of **June 23, 1999.**

Specification

The title of the invention has been amended to recite: 'Nucleic acids encoding PRO830' that is more descriptive of the invention.

The disclosure was objected to by the Examiner as containing "embedded hyperlink and/or other form of browser-executable code." The foregoing amendment to the specification which delete all embedded hyperlinks, is believed to overcome the present objections.

Accordingly, Applicants believe that all objections to the specification has been overcome.

Information Disclosure Statement

Applicants submit an IDS separately enlisting references recited in the Blast report filed 3/25/2002 in order to be compliant with 37 C.F.R. § 1.98(a)(1). Consideration of this Information Disclosure Statement is respectfully requested.

Claim Rejections – 35 U.S.C. §112, First Paragraph- Enablement

Claims 119-123, 132-138 are rejected under 35 U.S.C. §112, first paragraph, because, according to the Examiner, the specification while being enabling for a nucleic acid encoding a full length PRO830 protein of SEQ ID NO: 175, or a nucleic acid of SEQ ID NO: 174, does not reasonably provide enablement for a nucleic acid of at least 80-99% identity to SEQ ID NO: 174, or a nucleic acid of at least 80-99% identity to a nucleic acid encoding SEQ ID NO: 175. The claims were rejected for being overly broad since, allegedly, insufficient guidance was provided as to which nucleic acids encode variant polypeptides which retain the characteristics of PRO830. Fort the reasons indicated below, Applicants respectfully traverse this rejection.

Initially, Applicants submit that without acquiescing to the propriety of this rejection, Applicants have amended Claims 119-123 to recite a functional recitation: "wherein said nucleic acid is amplified in lung tumors." The instant nucleic acids are useful, for example, for the diagnosis of lung cancer based on their amplification in lung cancer. Based on the instant disclosure which details how to make and use nucleic acid variants (see pages 308-311), the functional recitation in the claims, and the advanced knowledge in the art at the time of filing, one skilled in the art would know exactly what nucleic acid variants the instant claims encompass and would know how to make and use these nucleic acids for the diagnosis of lung cancers without undue experimentation. Further, the cancellation of claims 127-128 and 132-134 without prejudice or disclaimer, renders this rejection moot to these claims.

Thus, Applicants believe that these rejections under 35 U.S.C. §112, first paragraph, should be withdrawn.

Claim Rejections – 35 U.S.C. §112, First Paragraph - Written Description

Claims 119-123 and 132-138 are rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. The Examiner says that "the claims are drawn to nucleic acids at least 80-99% identical to SEQ ID NO: 174 or SEQ ID NO: 175 and are thus genus claims. The specification and claims do not indicate what distinguishing attributes (are) shared by the members of the genus." Applicants respectfully traverse this rejection to the pending claims.

The Legal standard for Written Description

The well- established test for sufficiency of support under the written description requirement of 35 U.S.C. §112, first paragraph, is whether the disclosure "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *In re* Kaslow, 707 F.2d 1366, 1375, 212 USPQ 1089, 1096 (Fed. Cir. 1983); see also Vas-Cath, Inc. v. Mahurkar, 935 F. 2d at 1563, 19 USPQ2d at 1116 (Fed. cir. 1991). The adequacy of written description support is a factual issue and is to be determined on a case-by-case basis. see *e.g.*, Vas-Cath, Inc. v. Mahurkar, 935 F. 2d at 1563, 19 USPQ2d at 1116 (Fed. cir. 1991). The factual determination in a written description analysis depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. Union Oil v. Atlantic Richfield Co., 208 F. 3d 989, 996 (Fed. Cir. 2000).

Arguments

As noted above, whether the Applicants were in possession of the invention, as of the effective filing date of an application is a factual determination, reached by the consideration of a number of factors including the level of knowledge and skill in the art, and the teaching provided by the specification. The inventor is not required to describe every single detail of his/her invention. An Applicant's disclosure obligation varies according to the art to which the invention pertains.

The present invention pertains to the field of recombinant DNA/protein technology. It is well established that the level of skill in this field is very high since a representative person of

skill is generally a Ph.D. scientist with several years of experience. Accordingly, the teaching imparted in the specification must be evaluated through the eyes of a highly skilled artisan as of the date the invention was made. The instant invention, defined by the claims, concerns polypeptides having 80%, 85%, 90%, 95% or 99% sequence identity with the disclosed polypeptide sequence SEQ ID NO: 175 or nucleic acid of SEQ ID NO: 174 and further recites the recitation: "wherein said nucleic acid is amplified in lung tumors." Based on the detailed description of the cloning and expression of variants of PRO830 in the specification, the description of the gene amplification assay and description of testing the ability of test variant polypeptides in the assay, the actual reduction to practice of sequences SEQ ID NO: 175 and 174 and the functional recitation in the instant claims, Applicants submit that one of skilled in the art would know that Applicants possessed the invention as claimed in the instant claims.

Hence, Applicants request that this rejection be withdrawn.

Claim Rejections – 35 U.S.C. §112, First Paragraph- Enablement

Claims 137 is rejected under 35 U.S.C. §112, first paragraph, because, according to the Examiner, the specification while being enabling for a host cell in culture, does not provide enablement for *in vivo* transfection.

Claim 137 has been amended to recite "isolated host cell" as recommended by the Examiner and hence this rejection must be withdrawn.

Claim Rejections – 35 U.S.C. §102(a)

Claims 119-122, 132-138 are rejected under 35 U.S.C. §102(a) as being anticipated by Sehra *et al.* (dated 2001).

As discussed under the priority section above, the effective filing date of the instant application is at least **June 23, 1999**, which predates Sehra. Therefore, Applicants submit that Sehra is not prior art and hence request that this rejection be withdrawn.

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. **08-1641**, referencing Attorney's Docket No. **39780-2730 P1C52**.

Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: August 19, 2004

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